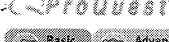


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Rule 56: Duty of candor and good faith

Howard M Eisenberg. Biopharm. Cleveland: Nov 2000. Vol. 13, Iss. 11; pg. 64, 3 pgs

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Subjects:

Disclosure, Patents, Applications, Rules, Fines & penalties

Companies:

Patent & Trademark Office (NAICS: 926150)

Author(s):

Howard M Eisenberg

Article types:

Feature

Publication title:

Biopharm. Cleveland: Nov 2000. Vol. 13, Iss. 11; pg. 64, 3 pgs

Source Type:

Periodical

ISSN/ISBN:

10408304 ProQuest document ID: 68802385

Text Word Count

1446

Article URL:

http://gateway.proquest.com/openurl?ctx_ver=z39.88-

2003&res_id=xri:pqd&rft_val_fmt=ori:fmt:kev:mtx:journal&genre=article&rft_id=xri:pqd:did=00000006

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Abstract (Article Summary)

Failure to disclose information to the Patent Office during prosecution of a patent application can result in severe penalties, including the unenforceability of the patent. Rule 56 imposes a duty of candor and good faith in dealing with the Patent Office. It is important to be aware of who is included in the duty of candor and good faith and what information must be disclosed to comply.

Full Text (1446 words)

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[Headnote]

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[Headnote]

Failure to disclose information to the Patent Office during prosecution of a patent application can result in severe penalties, including unenforceability of the patent

The Code of Federal Regulations (CFR) 37, Part 1.56, known as "Rule 56," imposes "a duty of candor and good faith" in dealing with the Patent Office during the period of examination of a patent application. This duty requires certain individuals to disclose any information they are aware of that is material to the issue of patentability. Failure to do so can result in severe consequences, including unenforceability of any patent that might issue from the application. It is important to be aware of who is included in the duty of candor and good faith and what information must be disclosed to comply.

Presumed Valid

There are positive reasons to disclose information to the Patent and Trademark Office (PTO). Legally, a patent is presumed valid with respect to information or prior art considered by the PTO during examination of an application. Someone accused of infringing a patent faces a very difficult burden in trying to prove that an issued patent is invalid based on prior art or other information that was considered by the PTO during examination. The burden of proof to prove patent invalidity is much lower if based on information that had not been considered by the PTO.

The regulations state that any individual associated with the filing or prosecution of a patent application is included in the duty. That includes each of the named inventors, their attorneys or agents involved in the patent preparation or prosecution, and anyone else who is substantively involved in the preparation of the application and who is associated with the inventor, the assignee, or anyone who has a duty to assign the application. This does not mean that everyone associated with the assignee is included, but all of those individuals who are involved in the patenting process must comply with Rule 56.

Because penalties are severe for failure to comply, it is best to err on the safe side and disclose all information that could be relevant in deciding whether or not a patent should be granted. Only information that is "material to patentability" must be disclosed. Information that is cumulative need not be submitted if it repeats information already disclosed to the PTO.

Arguably Relevant

Several issues arise regarding Rule 56. The first is, How can I know whether information is considered to be "material to patentability?" Unfortunately, there is no easy answer. Most courts use an expansive test in which information is considered material if it is arguably relevant to the issue of patentability and therefore might have affected the decision of the PTO (1). Other courts use a more lenient "but for" test: Information is considered to be material if the invention would not have been patented if the information had been supplied to the Patent Office.

Another question raised by Rule 56 is, Under what circumstances does the duty of candor apply? The first circumstance occurs when a patent application is filed. The inventors individually sign a statutory oath of inventorship stating that they are the first and original inventors of the claimed invention and acknowledging that they have a duty under Rule 56 to disclose information material to patentability. That includes information such as prior sale or public use of the invention (2).

Prior Art

Rule 56 also requires the submission of known relevant prior art to the PTO. The applicant is under no obligation to search for relevant prior art. However, any known material prior art, including U.S. or foreign patents or published patent applications, scientific and other journal articles, brochures, and web sites, must be submitted. That is submitted to the PTO in the form of an "information disclosure statement" (IDS). It is best to be over-inclusive when filing an IDS because the submission of a prior art document in it does not constitute an admission that the information is indeed relevant to the invention claimed. Rather, it is understood that in striving to comply with Rule 56, an applicant often will disclose publications that are distant from the claimed invention.

Duty with respect to prior art extends to more than submitting it to the PTO. If the examiner mistakenly interprets a prior art reference in the applicant's favor, the applicant must correct the examiner. The applicant also must explain the relevance of any publication submitted in a foreign language or of any particularly relevant prior art document if it is being submitted as part of a long list of documents.

Affidavits Submitted

Rule 56 also applies to the submission of affidavits or declarations concerning the date of invention or factual evidence, such as test data to establish patentability. Providing false or misleading information is an obvious violation of the duty of candor. It is important to realize that omitting information can be considered a violation of Rule 56. For example, failure to disclose that an individual signing a declaration has an interest in the invention has been found to violate Rule 56. Violations also have been found when successful test data were submitted, but the fact that there had been several unsuccessful tests was not disclosed. In such a situation, it is best to disclose the unsuccessful tests and explain why the failures occurred and why they should not negatively affect patentability.

Usually, failure to disclose material information, or providing misleading or false material information, referred to as

""inequitable conduct," is discovered only after a patent issues, typically in the context of litigation. If inequitable conduct is found during prosecution of a patent application, a patent examiner may strike the application. In litigation, a court may hold a patent to be invalid or unenforceable because of the applicant's inequitable conduct. Such a finding may also provide the basis for awarding attorney's fees to the defendant in an infringement suit. The Supreme Court also has found that fraudulent procurement of a patent through inequitable conduct can form the basis of an antitrust suit (3).

The Good News

Don't despair. There is good news. A punishable violation of Rule 56 requires more than an honest mistake by the applicant. It requires that the omission or submission of false information was done with an intent to deceive the examiner. The duty extends only to information that is known to the applicant or the other listed individuals. There is no duty to make a search of the prior art. To invalidate a patent for inequitable conduct, a defendant must prove to the court that the patentee knew of material information and failed to disclose the information with the intention to deceive the examiner.

So what should you do, as an applicant for a patent, to make sure that you comply with the duty of candor and good faith? I suggest that you provide your patent attorney with any publications that, either by themselves or in combination with one or more other publications, might possibly suggest your invention. It's always best to submit more information than necessary rather than less. Inform your patent attorney of any prior use or sale of the invention or of anything that might include the invention. Let your attorney make the decisions about what to disclose to the PTO. Also, be complete in the information that is submitted in the form of affidavits or declarations, including any affiliation with the inventors or interest in the subject matter of the invention, and make sure that any statements regarding successful tests are accurate and complete, especially regarding any test failures.

Although Rule 56 might at first appear frightening, it really is not difficult to comply with. What is required is a positive determination to share with the PTO any information that you have concerning your invention. There really is no downside to submitting information to the PTO. If you are unsure whether or not to submit a particular piece of information, err on the side of providing more information than necessary. If you act with the intent to fully disclose, the chances are small that you ever will be found in violation of the duty of candor and good faith.

[Reference]

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